DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 28, 2015

Covidien LLC
Rachel Silva
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K150251
Trade/Device Name: Barrx Anorectal RFA Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: June 25, 2015
Received: June 26, 2015

Dear Rachel Silva,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, PhD
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K150251

Device Name
Barrx™ Anorectal RFA Wand

Indications for Use *(Describe)*
The Barrx™ Anorectal RFA Wand is indicated for use in the coagulation of bleeding and non-bleeding sites in the anal canal and rectum, including but not limited to, arteriovenous malformations, angiomata, angiodysplasia, and radiation proctitis (RP).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) Summary

Submitter's Name and Address:
Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person:
Rachel Silva
Senior Regulatory Affairs Specialist
Phone: (408) 328-7359
Fax: (408) 328-7359

Date Prepared: July 2, 2015

Name of Device:
Proprietary Name: Barrx™ Anorectal RFA Wand
Common/Usual Name: Electrosurgical Coagulation Catheter
Classification Panel: General & Plastic Surgery
Device Regulation: 21 CFR 878.4400, Class II
Product Code: GEI

Establishment Registration Number, Owner/Operator Number:
Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Predicate Device(s):
K112454 Barrx™ 60 RFA Focal Catheter by Covidien, Formerly BÂRRX MEDICAL, Inc.

Device Description:
The Barrx™ Anorectal RFA Wand is a sterile, single-use, bipolar device used to deliver radiofrequency (RF) energy to treatment tissue in the anal canal and rectum. The design of the Barrx™ Anorectal RFA Wand is a modification to the legally marketed Barrx ™ 60 RFA Focal Catheter predicate device. The Barrx™ Anorectal RFA Wand design has a rigid distal shaft with handle which allows for targeted use in the anal canal and rectum. The device is used exclusively with the Barrx™ Flex RFA Energy Generator (K092487).

Indications for Use:
The Barrx™ Anorectal RFA Wand is indicated for use in the coagulation of bleeding and non-bleeding sites in the anal canal and rectum, including but not limited to, arteriovenous malformations, angiomata, angiodysplasia, and radiation proctitis (RP).

Technological Characteristics of the Device Compared to Predicate Device
The Barrx™ Anorectal RFA Wand has the same technological characteristics as the predicate device; Barrx™ 60 RFA Focal Catheter. Both devices are sterile, single use, bipolar devices that have Electrically Erasable Programmable Read-Only Memories (EEPROMs) which connect to the Barrx™ Flex RFA Energy Generator. Both devices have similar construction, energy type, and principles of operation.

Principles of Operation
The Barrx™ Anorectal RFA Wand is used in connection with the Barrx™ Flex RFA Energy Generator. Once the device is connected, the EEPROM is read by the generator, recognizes the device, and determines the operation parameters.

The Barrx™ Anorectal RFA Wand has the same principle of operation as the Barrx™ 60 RFA Focal Catheter predicate device. Both devices use the same cap with electrode, use RF energy, and achieve similar ablation depths. Both devices are used with the Barrx™ Flex RFA Energy Generator where the operational settings are the same. Operation parameters for each device are stored in the device EEPROM connector.

Performance Data
Performance testing for the Barrx™ Anorectal RFA Wand consisted of in-vitro functional testing, biocompatibility testing, sterilization assessment, packaging validation, shelf life testing, electrical safety testing, and user validation. Results of performance testing demonstrate performance equivalence for the Barrx™ Anorectal RFA Wand when evaluated against the predicate device.

Conclusion
Covidien llc considers the Barrx™ Anorectal RFA Wand to be substantially equivalent to legally marketed predicate device Barrx™ 60 RFA Focal Catheter (K112454). Test results and compliance to applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.